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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,384	06/24/2008	Stephan Olson	0225-004	1285

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EXAMINER	
DOUKAS, MARIA E	
ART UNIT	**PAPER NUMBER**
3767	

NOTIFICATION DATE	DELIVERY MODE
11/20/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

tammy@ppglaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,384	OLSON, STEPHAN	
	Examiner	Art Unit	
	MARIA E. DOUKAS	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/16/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 16 recites the limitation "a needle shield link" in the last line of the claim. There is insufficient antecedent basis for this limitation in the claim. Claim 16 depends from independent claim 14 and not dependent claim 15, where the needle shield link is first mentioned.

3. Claim 22 recites the limitation “the inwardly extending stop members of the dose activating means” in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

4. Claim 23 recites the limitation "the outwardly extending knob" in the second line of the claim; “the inwardly extending knob of the needle shield link” in the third line of the claim. There is insufficient antecedent basis for this limitation in the claim.

5. Claim 25 recites the limitation "the second set of ledges" in the second line of the claim; “the inwardly extending knob of the needle shield link” in the sixth line of the claim. There is insufficient antecedent basis for this limitation in the claim.

6. Claims 25 and 26 recite the limitation "the guide knobs" in the second lines of the claims. There is insufficient antecedent basis for this limitation in the claim.

7. Claim 26 recites the limitation "the other side of the ridges" in the second and third lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 14, 16, 17, 19-21 are rejected under 35 U.S.C. 102(e) as being anticipated by WO 2004/028598 to Karlsson (Karlsson).

In Reference to Claim 14

An injection device 10 comprising: a main body (main housing 12), a needle shield unit slidaby arranged in the body (needle shield 34), a cartridge (container 30) containing medicament, a plunger (drive rod 42) operatively arranged to the cartridge for ejecting the medicament through a needle (needle 28) and arranged on its upper part with a number of outwardly extending stop members (area between grooves 45; Figure 2B and threads on drive rod), spring means arranged to the plunger for operating the plunger (actuating spring 78), a dose activating means (mode selector 88), a needle

shield spring (spring 58) arranged to act on the needle shield unit, a first tubular member (assembly of lock nut 46 surrounded by lock sleeve 48 and dose actuating sleeve 50) rotationally and slidably arranged inside the needle shield unit, wherein it comprises a number of ridges and protrusions on the outer surface (protrusions 54 on forwardly directed tongues 56) that cooperate with guide members (recesses 38) on the inner surface of the needle shield unit (p. 7, lines 14-17) and ridges and protrusions on the inner surface of the first tubular member (tabs or protrusions 47 on inner surface of lock nut 46) that cooperate with outwardly extending stop members of the plunger (p. 6, line 31-p. 7, line 2), and a second tubular member (dose nut 62) arranged inside the housing, wherein it comprises a number of ridges and protrusions on the inner and outer surface (threads 67 on inner surface and grooves or splines 65) capable of setting and delivering a certain preset dose (p. 7, lines 23-32).

In Reference to Claim 16

The device of claim 14 (see rejection of claim 14 above) wherein the needle shield unit is arranged to be in a retracted position and to be held in this position against the force of the needle shield spring (p. 9, lines 6-8).

In Reference to Claim 17

The device of claim 14 (see rejection of claim 14 above), wherein the needle shield unit is arranged to be in an extended position and held in this position by the force of the needle shield spring (p. 9, lines 24-27; p. 12, lines 13-16).

In Reference to Claim 19

The device of claim 14 (see rejection of claim 14 above), wherein step-like inwardly extending ledges (threads 67 on inner surface of second section 66) are arranged to be positioned in line with the outwardly extending stop members of the plunger (threads on drive rod 42) for permitting different lengths of movement of the plunger and thus different doses of the medicament (p. 10, lines 5-12, whereby depending on the amount the dose setting knob is rotated the dose nut will move a certain distance along the drive rod thereby controlling the length of movement of the drive rod and the dose of medicament delivered).

In Reference to Claims 20 and 21

The device of claim 19 (see rejection of claim 19 above) wherein the step-like inwardly extending ledges are arranged on the inner surface of the second tubular member (dose nut 62). Therefore, the ledges are arranged between the dose activating means (dose setting knob 84) and the first tubular member as the dose nut is positioned between these two components (Figure 1A).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 15 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson.

In Reference to Claim 15

Karlsson teaches the device of claim 14 (see rejection of claim 14 above) but fails to teach wherein the needle shield unit comprises a needle shield link slidably connected to the needle shield, as the above described embodiment has the needle shield as one unit. Karlsson does teach that the needle shield can be constructed in two parts, a lower and upper part (p. 19, lines 19-23) in order to provide a lower part that can be locked in position to minimize the risk of needlestick injections (p. 19, lines 10-12) and this would therefore provide the upper part as the needle shield link.

In Reference to Claim 24

Karlsson teaches the device of claim 15 (see rejection of claim 15 above). Karlsson further teaches wherein the needle shield is arranged with guide knobs (tongues 36A, B containing grooves 38) that run along a guide surface (protrusions 54 on tongues 56) on the outer surface of the first tubular member and can cause the first tubular member to rotate in relation to the needle shield (p. 7, lines 8-14, whereby the dose actuating sleeve, which is part of the first tubular member, is capable of rotating so that as the needle shield is extended it would be capable of rotating in relation to the shield).

In Reference to Claim 25

Karlsson teaches the device of claim 15 (see rejection of claim 15 above). Karlsson further teaches wherein the guide knobs (tongues 36A, B containing grooves 38) of the needle shield run along ridges (protrusions 54) on the outer surface of the first tubular member when the needle shield is retracted (p. 11, lines 28-33). This retraction allows the dose actuating sleeve and connected lock sleeve 48 to also move backwards into the device. The first tubular member (lock sleeve 48 portion) is now free to rotate and the plunger's (drive rod 52) outwardly extending stop members (area between grooves 45) slip off the protrusions 47 on the first tubular member (lock nut 46 portion) to allow the drive rod to move forward and dispense the medicament (p. 11, line 18-p. 12, line 9).

In Reference to Claim 26

Karlsson teaches the device of claim 15 (see rejection of claim 15 above). Karlsson further teaches wherein the needle shield has tongues 36A, B containing grooves 38 that fit into protrusions 54 in the first tubular member (dose actuating sleeve 50 portion), which is capable of locking the needle shield in the extended position (p. 12, lines 13-17). Although Karlsson teaches grooves in the needle shield and protrusions in the dose actuating sleeve, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have reversed the parts to have the grooves in

the dose actuating sleeve and the protrusions in the shield, since it has been held that a mere reversal of parts involves only routine skill in the art (see MPEP §2144.04).

In Reference to Claim 27

Karlsson teaches the device of claim 25 (see rejection of claim 25 above). Karlsson further teaches wherein guide knobs of the needle shield (areas surrounding recesses 38) pass outwardly protruding acting snaps (ledges 96) to lock the needle shield in an extended position (p. 11, lines 13-16).

12. Claims 18, 22, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Karlsson in view of U.S. Patent No. 5,304,152 to Sams (Sams).

In Reference to Claim 18

Karlsson teaches the device of claim 14 (see rejection of claim 14 above) and further teaches wherein the dose activating means is arranged with inwardly extending stop members (protrusions 90). Karlsson fails to teach wherein the stop members cooperate with the stop members on the plunger. Sams teaches an injection device that has a plunger 23 with threads 33 and also teaches a second threaded member 22 with threaded segments 29 that allows interaction of the threads 33 with threads 29 in order to ensure the correct measured dose is dispensed (col. 6, lines 13-19).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mode selector 88 of Karlsson to have threads

as taught by Sams that could interact with the threads on the drive rod 42 in order to ensure the correct measured dose is dispensed (col. 6, lines 13-19). The modified device of Karlsson would be capable of holding the plunger and spring means in a tensioned locked position, as priming rotation of the mode selector 88 causes the dose actuating sleeve 50, lock sleeve 48, and needle shield 34 to be pulled backwards and tensioned to enable an injection to occur (p. 10, lines 21-30).

In Reference to Claim 22

Karlsson teaches the device of claim 14 (see rejection of claim 14 above) and further teaches wherein the dose activating means (mode selector 88) is turnable from a locked position to an optional dose position (p. 8, lines 24-31). Karlsson also teaches wherein during injection, the stop members of the plunger abut ledges on the inner surface of the first tubular member thereby pushing the plunger towards the cartridge to expel medicament through the needle (p. 11, line 18-p. 12, line 11). Karlsson fails to teach interaction between stop members on the mode selector and stop members on the drive rod. Sams teaches an injection device that has a plunger 23 with threads 33 and also teaches a second threaded member 22 with threaded segments 29 that allows interaction of the threads 33 with threads 29 in order to ensure the correct measured dose is dispensed (col. 6, lines 13-19).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the mode selector 88 of Karlsson to have threads as taught by Sams that could interact with the threads on the drive rod 42 in order to

ensure the correct measured dose is dispensed (col. 6, lines 13-19). The modified device of Karlsson would be capable of holding the plunger and spring means in a tensioned locked position, as priming rotation of the mode selector 88 causes the dose actuating sleeve 50, lock sleeve 48, and needle shield 34 to be pulled backwards and tensioned to enable an injection to occur (p. 10, lines 21-30). After priming, when an injection is to occur, the threads of the plunger would slide off the threads of the mode selector so that the plunger could advance to expel the medicament.

In Reference to Claim 23

Karlsson in view of Sams teaches the device of claim 22 (see rejection of claim 22 above). Karlsson further teaches wherein turning of the mode selector 88 causes the outwardly extending knob (protrusion 90) to move out of contact with the recesses 92 in the main housing and the dose actuating sleeve 50 (Figure 4C), which moves the protrusions 54 on the dose actuating sleeve within the grooves 38 of the needle shield 34 so that the force of the spring 58 can urge the needle shield to an extended position (p. 9, lines 24-27). The recesses 92 are located in the main housing of the device, however, it would have been an obvious matter of design choice to rearrange the parts of the device to have the recesses located within the needle shield, so that turning of the mode selector would enable the protrusion 90 to come out of contact with a recess within the needle shield and enable the positioning of the mode selector into the "locked" position to directly correspond to the needle shield being in an extended position to cover the needle (see MPEP §2144.04).

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. U.S. Patent No. 5,478,316 (Bitdinger) teaches an automatic injector with a needle shield and a driver and drive rod that are pushed forward to deliver medicament via a constant force spring.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA E. DOUKAS whose telephone number is (571)270-5901. The examiner can normally be reached on Monday - Friday 7:30 AM - 5:00 PM EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MD
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